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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/346,910 11/30/94 LIPTON

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EXAMINER

HM22/1121

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ART UNIT

PAPER NUMBER

1647

25

DATE MAILED:

11/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/346,910

Applicant(s)

Lipton

Examiner

Stephen Gucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/28/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 2-8, 11-12, & 14 is/are pending in the application.
- Of the above claim(s) 2-7 is/are withdrawn from consideration.
- ☒ Claim(s) 8, 11, & 12 is/are allowed.
- ☒ Claim(s) 14 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1647

Response to Amendment

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
4. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 encompasses every nucleic acid that contains at least 20 contiguous bases of clone ATCC 97525 which can selectively hybridize to nucleic acid encoding human MEF2C. Applicant states that the basis for claim 14 is found at page 4, lines 13-20 describing nucleic acid probes of at least 15-20 contiguous bases. However, a fair reading of the specification indicates that the Applicant does not have either verbatim or conceptual support for the recited limitation of a nucleic acid that would selectively hybridize to nucleic acid encoding human MEF2C. The instant specification teaches that:

“the probe is a portion of at least 15-20 contiguous bases of the nucleic acid encoding human 68075 [now called MEF2C]. This probe nucleic acid is used under standard stringent hybridization conditions to identify nucleic acid homologous to that encoding the human 68075. Not all such homologous sequences will encode a 68075 protein, but those

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which do can be identified by standard procedures.” (page 4, lines 13-20, underlining mine).

The specification discloses that probes of at least 20 bases cannot selectively hybridize to nucleic acid encoding human MEF2C because not all such sequences which the probe will hybridize to will actually encode human MEF2C, i.e. the hybridization is not selective because other standard procedures for identification must be performed. Therefore, a probe that meets the limitation of selective hybridization to an encoding nucleic acid sequence has not been taught by the disclosure. This is a new matter rejection.

5. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in ¶4 above, the specification discloses that probes of at least 20 bases cannot selectively hybridize to nucleic acid encoding human MEF2C because not all such sequences which the probe will hybridize to will actually encode human MEF2C, i.e. the hybridization is not selective because other standard procedures for identification must be performed. Therefore, a probe that meets the limitation of selective hybridization to an encoding nucleic acid sequence has not been taught by the disclosure. The specification provides no written description, no working examples, and no specific or substantial guidance as to how the skilled artisan could routinely make and use fragments of nucleic acid comprising at least 20 contiguous bases of clone ATCC 97525 wherein said nucleic acid is able to selectively hybridize to nucleic acid encoding human MEF2C because the instant disclosure admits that such nucleic acid fragments will hybridize

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nonselectively to nucleic acid that does not encode human MEF2C. Without such teachings, the disclosure does not place the invention into the hands of the skilled artisan without forcing undue experimentation to be performed in order to meet the limitations of the claim because it is entirely unpredictable how the claim limitations could be met given the teachings of the specification.

6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 is a very broad genus claim encompassing every nucleic acid that contains at least 20 contiguous bases of clone ATCC 97525. This would include every nucleic acid encoding every species homologue of MEF2C because the gene for MEF2C is highly conserved over a large range of species, including monkey, rat, mouse, dog, cow, and rabbit (Krainc et al., page 810). The instant specification describes the purification of partial nucleic acids encoding partial amino acid sequences of a single protein species, protein 68075 or human MEF2C, from a single animal species, human. The specification therefore has a single embodiment that has been shown to work as a transcription factor *in vitro*. It does not provide an adequate written description of any other animal species form of nucleic acids that encode a highly conserved MEF2C-like factor because the specification is silent as to what are the critical nucleic acid bases that are indicative or representative of the members of this very broad genus of nucleic acids that the claim encompasses. The claim also encompasses the genomic nucleic acid for human and other genomic animal species forms of MEF2C which also lack adequate written

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description because the specification is silent as to nucleic acid bases that make up the promoter regions, alternate splicing sites, introns, etc., that the genomic nucleic acid for MEF2C is comprised of and which would be encompassed by the instant claim. Given that the cDNA sequence of human MEF2C is over 3000 bases long, claims that encompass the genus of nucleic acids sharing only 20 bases with the deposited clone are not adequately described by the specification because the specification is completely silent as to any sequence description of the deposited clones, and the specification therefore cannot teach what chemical or structural characteristics or features of the single deposited species is representative of the genus.

7. Claims 8 and 11-12 are in condition for allowance.
8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0830 to 1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

November 18, 2000

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600